USE OF ALPHA-CHLORALOSE BY USDA WILDLIFE SERVICES TO IMMOBILIZE BIRDS

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Abstract: In 1992, the U. S. Food and Drug Administration (FDA) opened an Investigational New Animal Drug (INAD) file for the avian immobilizing agent, alpha-chloralose (AC) for the United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS). Currently, this INAD authorizes trained Wildlife Services (WS) personnel to use AC to immobilize and live-capture nuisance waterfowl (Anatidae spp.), American coots (Fulica americana), pigeons (Columba livia), common ravens (Corvus corax) and sandhill cranes (Grus canadensis). The use of AC has proven to be a valuable tool for WS and the number of birds captured with AC increased more than four-fold between 1993 and 2005. One requirement for using AC under the INAD is the submission of detailed semiannual reports documenting AC use to FDA. Based on the reports from October 2004 through September 2005, WS conducted 194 operations to immobilize and remove birds in 22 states, and used 413 grams of technical and 30 grams of tablets, totaling 443 grams of AC. Canada geese were the most frequently targeted species, accounting for 50% of all operations. The capture rate for all target birds using powdered AC was 80.2%, and 86.2% using tablets. The percent mortality of all target birds using powdered AC was 3.1%, and 4.9% using tablets.

Key words: alpha-chloralose, AC, birds, immobilizing agent

Proceedings of the 12th Wildlife Damage Management Conference (D.L. Nolte, W.M. Arjo, D.H. Stalman, Eds). 2007

INTRODUCTION

Trained United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS) personnel are authorized by the United States Food and Drug Administration (FDA) to use alpha chloralose (AC) to immobilize and live-capture specific species of nuisance birds under an Investigational New Animal Drug file (INAD 6602). The INAD file initially

allowed use on waterfowl (Anatidae spp.), American coots (Fulica americana) and pigeons or rock doves (Columba livia). In response to the growing need to facilitate scientific research and assist with bird conservation programs, APHIS later requested and was granted approval by FDA to add common ravens (Corvus corax) and sandhill cranes (Grus canadensis) to the list of allowable species under INAD 6602. In addition, special one-time uses were also

granted by FDA for operations involving Indian peafowl (*Pavo cristatus*), American crows (*Corvus brachyrhynchos*), black-crowned night herons (*Nycticorax nycticorax*), red-winged black birds (*Agelaius phoeniceus*), mitered conures (*Aratinga mitrata*), and wild turkeys (*Meleagris gallopavo*).

This analysis summarizes reporting year (October 1, 2004 through September 30, 2005) of AC use to immobilize birds by WS. Included are descriptions of the distribution of AC use by WS by state and time of year; the target species of the operations, including the frequency of operations targeting each species, number of birds, proportion of birds captured at a site, percent mortality; and nontarget impacts, including species. number, and mortality.

REGULATORY HISTORY

In 1988 and 1989, early trials were conducted by the Denver Wildlife Research Center (DWRC), now the National Wildlife Research Center (NWRC) to determine if AC could be used in the field to safely and effectively capture nuisance geese, ducks, coots and pigeons. On October 30, 1989, the DWRC, and its contract consultant, Wildlife Pharmaceuticals, Inc. (Fort Collins, CO) submitted a request to the FDA to establish an INAD to allow capturing and relocating waterfowl and pigeons. The FDA opened an INAD file on April 3, 1990, allowing WS to use AC under INAD 6602 to develop research data. From 1990 to 1992, safety and efficacy studies were conducted by DWRC and submitted to FDA under an expedited review process. most effective dose was determined for capturing waterfowl and pigeons. DWRC conducted 11 field trials in 4 states, capturing 587 waterfowl and 1,370 pigeons with 8 % mortality for ducks, 0 % for geese, and 6 % for pigeons (Woronecki et al. 1992).

On October 18, 1991, the DWRC submitted a New Animal Drug Application (NADA) for AC that contained product identification, draft product labeling, analytical methods, and safety and efficacy data. In June 1992, FDA asked APHIS to withdraw the NADA, citing the narrow safety margin between the therapeutic and lethal doses of AC, and the lack of a regulatory mechanism to sufficiently limit authorized AC applicators. Alternatively, FDA offered to give APHIS a perpetually active INAD for waterfowl, coots and pigeons only, with conditions limiting AC access and use. Under these conditions: 1) AC use to capture the select bird species was permitted only under INAD 6602; 2) AC users must become certified by completing a WS training course on proper use of AC; 3) records of AC use must be maintained and submitted semi-annually to FDA; and 4) the Pocatello Supply Depot, Pocatello, ID (PSD) was to be the sole source of AC for the WS program. Further, it was determined that AC may not be administered during or 30 days prior to the start of the hunting season for populations of birds that could be hunted.

The FDA has continued to regulate the use of AC to immobilize certain bird species since 1992, and AC has proven to be a valuable tool for WS. In addition to addressing nuisance bird problems, AC has been used to facilitate scientific research, and assist bird conservation research programs. To address these needs, the FDA has authorized the addition of common ravens and sandhill cranes to the INAD, and has allowed special one-time uses for operations involving Indian peafowl, crows, black-crowned night herons, red-winged black birds, mitered conures, and turkeys.

METHODS

The AC use information for the reporting period October 1, 2004 through September 30, 2005 was obtained from the

USDA, APHIS, Office of Policy and Program Development, Environmental Services (ES), and each report form was retrieved from the WS Regulatory Correspondence Archive at the NWRC. One condition of the INAD 6602 requires semiannual reporting to FDA of all AC use. WS personnel complete report forms for each operation. Much of this information is entered into a database by ES for reporting purposes. This database served as the base information for analysis done for this manuscript. The report forms contained additional data used in this evaluation, but not required by FDA, and thus not entered into the database. The report forms also served to verify the database.

Two formulations of AC are available from the PSD. The initial formulation is a powder, first offered in 1992. In 2002, tablets became available in dosages 20, 40, and 60 mg, color coded for easy identification. The use of both formulations was examined in this analysis.

Data Collected

- 1. AC dose used to capture each species
- 2. Total quantity of AC used in this period
- 3. States where USDA/WS used AC
- 4. Characterization of AC use sites
- 5. Frequency of bird removal operations per species
- 6. Seasonal use of AC
- 7. Target bird capture efficacy and safety of AC use by WS
- 8. Nontarget species impacts during bird removal operations

Definitions

Operation: An operation is defined as a project to remove birds conducted on a

unique date at a given location. Removals of birds from the same site, on multiple days, are considered multiple operations.

Percent efficacy: The percent efficacy (or percent live capture) is a comparison of the number of target birds fed AC during an operation, and the number of birds captured alive.

Percent mortality: Mortality is a function of the number of target birds fed AC, and the number that died during operations. The cause of the death may be overdose, capture myopathy, or any unintended lethal event related to the operation.

Species grouping: Certain species of waterfowl were grouped together. All feral, hybrid and domestic geese breeds were classified as domestic geese, while Canada geese were considered separately. Similarly, all feral, hybrid and domestic ducks breeds (except domestic mallards) were classified as domestic ducks. Wild and domestic mallard ducks were simply classified as mallards.

RESULTS

AC Dose Used to Capture Each Species

Table 1 identifies the species authorized for capture under INAD 6602 as of 2007, and the most effective AC dose for safe capture. For waterfowl, the most effective dose is 30 mg/kg (Woronecki et al. 1992). The most effective doses for pigeons is 180 mg/kg (Belant and Seamans 1999), and the doses for other bird species range from 15 to 50 mg/kg, respectively (Belant et al. 1999, Knittle et al. 1994, Hayes et. al. 2003).

Table 1. Recommended AC doses to immobilize birds under INAD 6602.

Target Species	Most Effective AC Dose		
pigeons (rock doves)	180 mg/kg		
sandhill cranes	50 mg/kg		
ravens	47 mg/kg		
Canada geese	30 mg/kg		
ducks	30 mg/kg		
American coots	30 mg/kg		
swans	15 mg/kg		

Total Quantity of AC Used in This Period

In the period October 2004 through September 2005, USDA WS used approximately 443 grams of AC during capture operations. The powdered formulation is the most commonly utilized and represents 413 grams of the total, while 30 grams were in tablet form. AC discarded for reasons unrelated to a specific operational activity, or due the to

cancellation of an operation is not included in this total.

States Where USDA WS Use AC

Twenty-three states used AC in a total of 194 operations (Figure 1). The 4 states conducting the most operations were Kentucky (37), followed by Utah (26), and Arizona and Nevada (16 each).

Operations Using Tablets and Technical AC October 2004 - September 2005

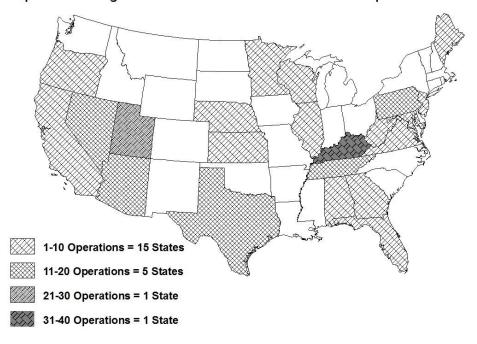


Figure 1. Distribution of AC use operations conducted in each state October 1, 2004 through September 30, 2005.

Table 2. Locations of bird immobilizing operations conducted by WS personnel October 1, 2004 through September 30, 2005.

Location	Number of Operations
business/office	25
parks/lakes	20
cemeteries	17
airports	17
golf courses	11
residential	11
unknown urban areas	8
marinas	6
hotels/resorts	6
wildlife areas	6
schools/campuses	4
agricultural areas	2
ZOOS	1
swimming areas	1
water treatment plants	1
	136

Operations using AC in Urban Areas October 2004 - September 2005

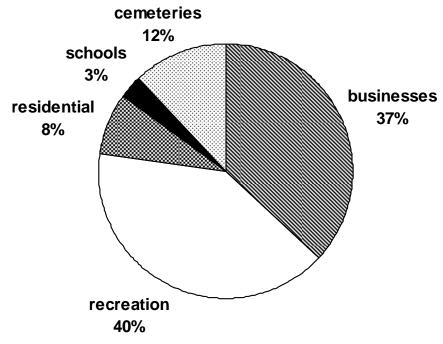


Figure 2. Frequencies of AC use operations in urban areas October 1, 2004 through September 30, 2005.

Characterization of AC Use Sites

The location of operations was determined from the project forms completed by the WS personnel. Out of the 194 operations, 136 forms were completed in sufficient detail to easily determine the use site (Table 2).

Of the 136 operations listed in Table 2, 94% were conducted in urban/suburban areas (Figure 2). The locations most often targeted for bird removal were sites used for recreation (40%) that were comprised largely of parks, lakes, golf courses, and hotels and resorts. These areas were followed closely by business related sites (37%) such as business and office complexes, and airports. Cemeteries, residential areas and schools comprised the remaining 23% of use sites.

Frequency of Bird Removal Operations per Species

Operations may target more that one species. Thus, a single operation may be represented more than once in this analysis. Canada geese are the most frequent target for removal, and were removed in 113 (50%) of all operations (Figure 3). Domestic ducks and mallards were the next most often targeted species in 54 (24%), and 34 (15%) of the operations respectively.

Seasonal Use of AC

The greatest use of AC occurred in March, April and May, and a spike was observed in December (Figure 4). The increased use in December was due to a large increase in operations caused by an emergency response to an oil spill on the Delaware River.

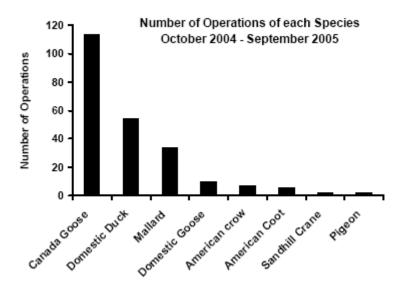
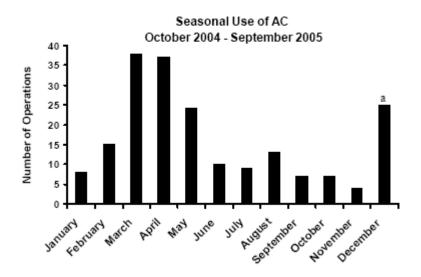


Figure 3. The number of AC operations targeting each bird species or grouping October 1, 2004 through September 30, 2005.



^a The increased use in December is due to a large increase in operations caused by an emergency response to an oil spill on the Delaware River.

Figure 4. Seasonal use of AC by month October 1, 2004 through September 30, 2005.

Table 3. Target species efficacy and mortality of birds captured October 1, 2004 through September 30, 2005.

	% Live Capture		% Mortality		
Species	Powdered AC	AC Tablets	Powdered AC	AC Tablets	
Canada Goose	84.5	78.0	3.3	0.0	
Domestic					
Duck	85.4	97.3	4.9	9.3	
Mallard	85.0	46.2 ^a	3.4	7.7 ^a	
Mean	84.9	86.2	3.8	4.9	

 $[\]overline{^{a}}$ Based on operations in which a total of 13 mallards were feeding, 6 were captured, and 1 died.

Overall Mean of all Species ^b	80.2 ^b	86.2	3.1 ^b	4.9
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^b Overall mean is calculated from all 9 bird species groupings that powdered AC was used to capture during the 2004 – 2005 reporting cycle.

Target Bird Efficacy and Safety of AC Use by WS

WS demonstrated successful live capture with low mortality using both formulations of AC during the 2004–2005 reporting cycle. The number of target birds captured using both formulations of AC was

2,971. The target species were Canada geese (976), domestic ducks (930), American coots (585), mallards (379), domestic geese (54), pigeons (30), American crows (12) and sandhill cranes (5). Tablets were used only in operations targeting immobilization of Canada geese, domestic

ducks and mallards. Thus these 3 groups were selected for comparison between operations using powdered AC and AC tablets (Table 3). The mean percent live capture and mortality for each of the 3 groups is presented, as well as the overall mean for all targeted species. For tablets, the means and overall means for all species are identical because both represent only 3 groups. However, the overall mean for all species of the powdered AC is the mean of the 9 species groups identified in Figure 3, while the mean is calculated for only the 3 groups shown in the table.

The tablet data for this period represent a relatively small number of operations. For example, only 6 of 13 mallards fed AC during 2 operations were live captured, and 1 died. In this case, the percent live captured was very low at 46.2%, but the sample size was also low. When all birds and both formulations are considered for the 1 year reporting cycle, the live capture efficiency was 80.2% when using powdered AC, and 86.2% when using tablets.

The mortality rate for domestic ducks was slightly higher for both formulations (4.9% for powder, and 9.3% for tablets) than for the other 2 primary species, or for all species combined. The

mean mortality rates for powder and tablet formulations of the 3 primary species were 3.8% and 4.9%, respectively. The overall mean mortality for powder use was 3.1%, and 4.9% for AC tablets. The mean mortality of mallards using tablets is also relatively high at 7.7%. However, this mortality rate is calculated from only 13 birds feeding, 1 of which died.

Nontarget Species Impacts During Bird Removal Operations

Nontarget species were divided into 2 classifications. "Regulatory Nontargets" are defined as those species that are immobilized and/or died during an operation, and are not target species under INAD 6602. These are in contrast to "Operational Nontargets", which are those species that may be immobilized with AC under the INAD, but are not the intended target species of an operation.

Most nontargets unintentionally fed AC, were exposed to baits containing the powder formulation (Table 4). Only 12 nontarget birds were fed AC during the reporting cycle, and 6 of those died. Five of the 6 birds that died were English sparrows, and the other was a wood duck. At least 2 carp also ingested bait, and their disposition is unknown.

Table 4. Nontarget species impacts (numbers of birds fed AC, bird deaths, and operations) October 1, 2004 through September 30, 2005.

	AC Formulation	Species	Number of Birds Feeding	Number of Bird Deaths	Number of Operations
Regulatory Nontargets ^a	Powder	English sparrow	5	5	1
		grackle	1	0	1
		carp	≥ 2	?	2
Operational Nontargets ^a	Powder	mute swan	1	0	1
		diving ducks	2	0	1 ^b
		wood duck	1	1	
		merganser	1	0	
	Tablet	American coot	1	0	1

^a 'Regulatory Nontargets' are defined as those species that are immobilized and/or died during an operation, and are not allowable species under INAD 6602. These are in contrast to 'Operational Nontargets', which are those species that may be immobilized with AC under the INAD, but are not the intended target species of an operation.

^b The nontarget diving ducks, wood duck and merganser were all captured during a single operation.

DISCUSSION

AC is an important tool for WS because it allows for the safe capture of birds in nuisance situations, when they are causing public health and safety concerns, and in emergency response situations such as oil spills. Its national importance is highlighted by its use in 22 states over the one year reporting period evaluated in this manuscript. While the application of AC is geographically broad, the amount used, only 443 g, is relatively small. This reflects the highly targeted application by trained applicators of this immobilizing agent.

AC was used primarily in areas with high public visibility. Because AC dosed birds generally become quiet and allow for low stress capture, the public readily accepts this method for removal of nuisance birds. There were no instances during this period were AC was used to immobilize birds in an agricultural setting.

Most operations occurred during March, April and May. The timing of the operations may be due in part, to the increased use of outdoor areas during spring. The decreased use in subsequent months may be influenced by the 30-day hunting restriction, disproportionately prohibiting use under many circumstances (Belant et al. 1999). The increased use documented in December 2004 was unexpected, but is due to a substantial increase in operations due to an emergency response to an oil spill on the Delaware River. AC was used to remove birds with oiled feathers, which were then transported to a bird rehabilitation facility.

The capture efficiency is derived from the percent efficacy, or percent live capture of birds. The overall capture efficiency of both powdered AC and AC tablets is greater than 80%. By definition, the most effective dose (MED) is the capture of 90% of the birds with no mortality. Therefore the capture efficiency in this period is an acceptable capture rate,

especially considering the narrow safety margin. Additionally, in many cases the cause of death during an operation is due indirectly to the drug (e.g., birds drown because they become unconscious while on water). Increasing the dose further could increase mortality to an objectionable level.

FDA has indicated since 1992 that they have serious concerns regarding the safety margin of AC. For example, the lethal dose at which 50% of the dosed birds die (LD₅₀) for AC in Canada geese is 53.9 mg/kg. The effective dose at which 50% of the birds are sedated (ED₅₀) is 15.1 mg/kg. Under operational field conditions, where a higher capture rate is desired, the MED for Canada geese is 30 mg/kg (Woronecki et al. 1992). Therefore, birds that receive two 30 mg/kg baits have at least a 50% chance of dying.

Belant et al. (1999) reviewed WS use of AC during 1994-1995. They reported mortality for all species at 5% when using powdered AC, the only formulation available in 1994-1995. In the analysis by Belant et al. (1999), mortality was measured by comparing the number of birds that died to the number captured. In the current analysis, the number of birds that died was compared to the number of birds feeding on the AC bait irrespective of capture. By comparison, the current analysis results in slightly lower mortality than the method of Belant et al. (1999) The overall percent mortality of target birds in this analysis is 3.1% for powdered AC and 4.9% for AC tablets when calculated on the number of birds fed. Recalculation of % mortality based on the number of birds fed AC, instead of the number captured, results in mortality rates of 3.8% and 5.7%, respectively. Regardless of the calculation method employed, both analyses indicate low mortality using AC to immobilize birds.

During the reporting year 2004-2005, the mortality for Canada geese was 3.3%

and 0% when geese were immobilize using powdered AC and AC tablets, respectively. Mortality of both domestic ducks and mallards was slightly higher, particularly for AC tablets where mortality was 9.3% and 7.7% respectively. In contrast, Belant et al. (1999) reported 3% mortality for mallards and 5% mortality for domestic mallards. The authors do note a trend of increased mortality when using bread baits due to birds getting more than 1 bait. That is consistent with the slight increase in mortality observed with tablet use (4.9%) in the current analysis, since tablets are used exclusively with bread baits. tablets were not available in 1994 and 1995, bread baits used during this period were prepared with the powdered formulation. Therefore, the relative importance of formulation and bait type remains unclear.

Belant et al. (1999) also reports a 17% mortality rate for 200 muscovys captured during 11 operations was ≤ 17% for 36 ducks other than muscovys captured during 4 operations. These percentages are relatively high compared to overall mortality of 3% (Belant et al. 1999) in 1994-1995, and the 3.1% to 4.9% in the current analysis. While most of these muscovys and other ducks were captured with bread baits, it seems unlikely that this correlation alone reflects the increased mortality. The number of birds fed AC, especially mallards, was low during the 2004-2005 reporting period. Thus, further analyses of bait type and AC formulation over multiple years are needed to confirm and explain the observed mortality seen in some duck species.

There were few nontarget birds inadvertently fed AC bait in the 2004-2005 reporting year (12 birds) compared to 1994 through 1995 (102 birds per 2 years) (Belant et al. 1999). Further analysis of multiple years of data are needed to determine if there is a trend toward decreased risk to nontargets as WS biologists gain experience with the use of AC. The powder

formulation may present a greater risk to nontargets than the tablets. This might be due to accidental ingestion of part of a bread bait, which could cause narcosis or a toxic effect, particularly in small birds, as shown by the deaths of all 5 English sparrows that ingested powdered AC formulated in bread baits during 1 operation. It is difficult to access the relative risk to nontargets from powdered AC compared to tablets in this analysis, since the number of nontargets was very low. However, the risk from AC tablets to small birds, such as song birds, is presumed to be extremely low because the tablets are too large to be ingested by most small bird species. No song birds ingested tablets during the 2004-2005 reporting year.

Despite the narrow safety margin of AC, WS biologists have demonstrated the ability to use this tool effectively and safely. The impact on nontarget species is generally low, since there are few nontarget incidents. The success of WS operations using AC is likely due to many factors. Under INAD 6602, FDA required that only trained WS personnel would be allowed to immobilize birds with AC. In response, WS developed an effective training program. Proper training in combination with several years of experience demonstrates that AC can be used to immobilize birds with few adverse impacts.

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